Laboratory Patch 21
aka “Reference Lab Interface”

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Agenda

- What is the interface?
- Release date
- Design of the interface
- What does the interface do?
- RPMS system requirements
- Types of interfaces
- Connectivity choices
- Steps to implementation
- Initial setup steps
- Final setup steps
- Some examples of the interface “in action”

What is lab patch 21?

Lab patch 21

- Lab patch 21 is designed to be a part of the RPMS Lab Package.
- Patch 21 consists of an interface engine known as the Generic Interface System (GIS).
- The GIS component is the actual “engine” of the interface and works to transfer data to and from a reference laboratory.
- Imagine a giant analyzer in your lab, yet you don’t see it.
- Two types of interfaces:
  - Uni-directional passes results from a ref lab to PCC database
  - Bi-directional transmits orders electronically **AND** receives results

So…when does the interface hit the streets?

Lab patch 21 projected release date

- Beta testing is complete and we have an interface ready for national release.
- Because OIT does not have the resources to train and deploy the interface, we are tasking CMI to do this for us at least for the first year.
- So…release date is a moving target at least for now but I feel comfortable releasing it next week.

Ref lab deployment plan

- CMI will conduct 12 Area office training sessions and deploy the interface at 15 sites.
- The “chosen 15” are expected to help other sites install and implement this interface.
- The “EHR” model of capacity building within IHS and tribal sites.
- I would like to foster collaboration and coordination among sites and areas and the end result is to deploy this application to as many sites as want it.
- We are all in this together. OIT is not the cash cow it used to be and the fact is, there is no funding available anywhere for extensive training and deployment of major applications.

Some facts regarding implementation

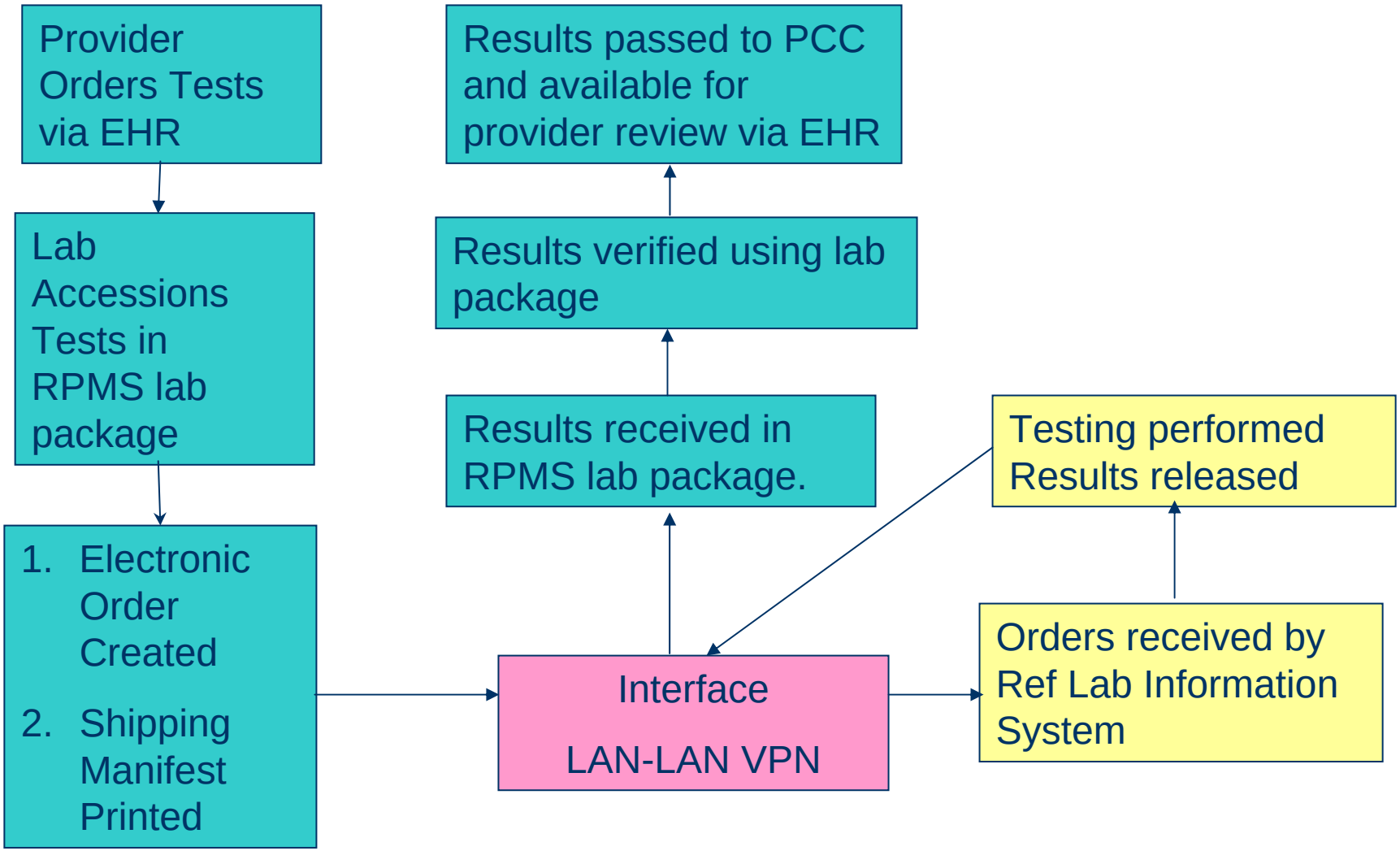
- Implementation of the interface is time-intensive & requires the coordination of several parties; the facility, OIT network staff, ref lab network staff, ref lab project officer, site project officer.
- Tribes exercising the 638 option have depleted the OIT budget for training and implementation.
- We estimate that it will take a site approximately 6-10 weeks from the time we actually “walk in the door” to the time a site can order and result one sendout lab.
- Collaboration and coordination.

What does the interface do?

- Automates the electronic ordering (bi-directional mode only) of labs and the automatic receipt of test results from a reference lab (uni-directional & bi-directional).

How does it work?

Design of the Interface (bi-directional)



As a site manager, I want to know what the RPMS system requirements are?

RPMS system requirements

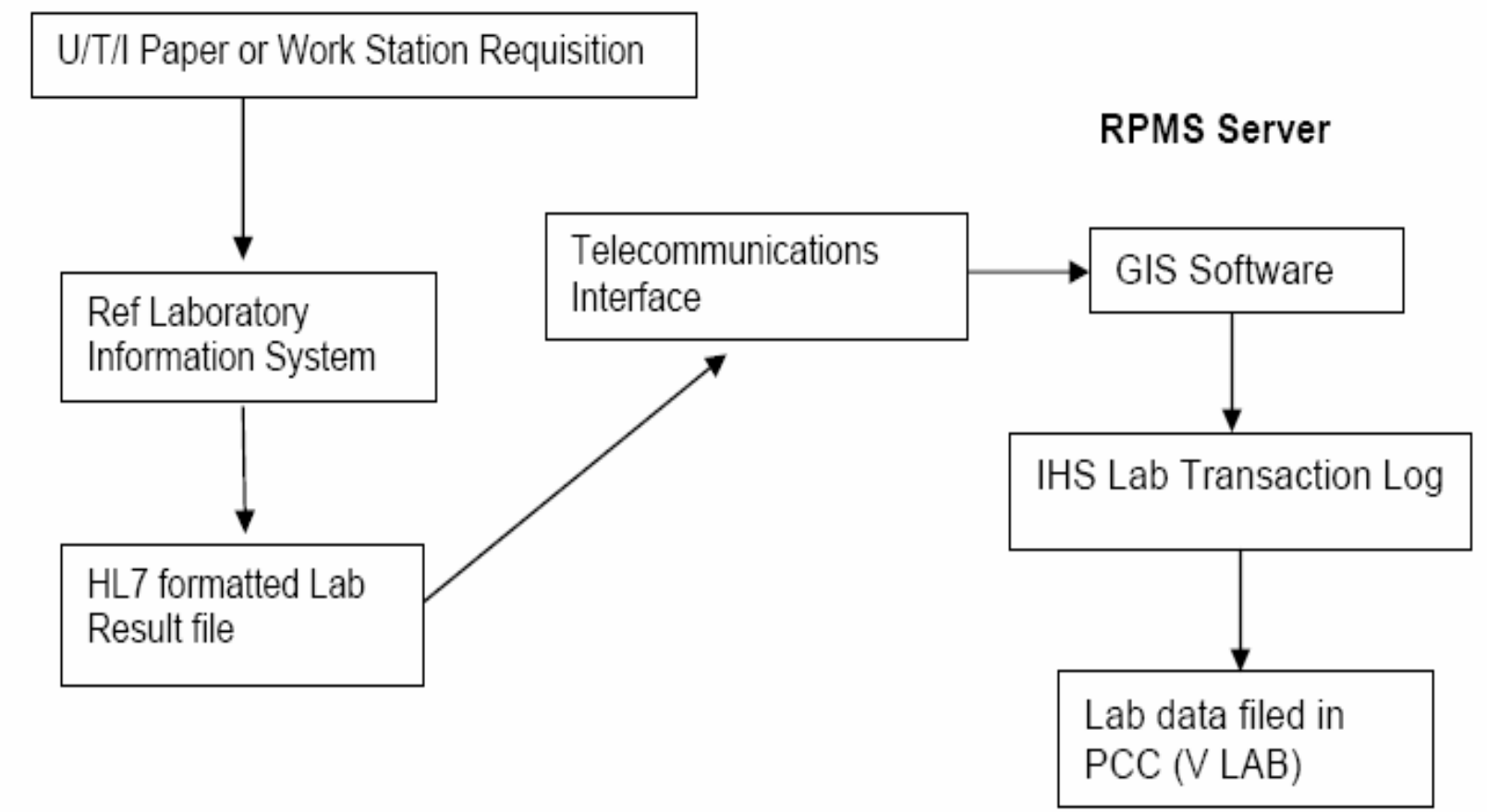
- RPMS Laboratory Package Version 5.2 through patch 20.
- GIS Version 3.01 patch 13 and 14.
- Kernel Version 8.0 through patch 8.
- FileMan Version 22 through patch 1.

Two types of interfaces: Uni-directional and Bi-directional

Uni-directional interface

- Facility orders a “sendout” test but does NOT send the order electronically, instead orders via telnet or paper requisition
- Facility receives results from reference lab electronically & passes that data directly into the RPMS PCC database.
- Designed as a replacement for PCC Data Entry.
- Results are available via Health Summary and database searches such as Q-Man.
- Results **NOT** available for viewing via EHR in this mode.
- Reference ranges and units stored with patient results in PCC.

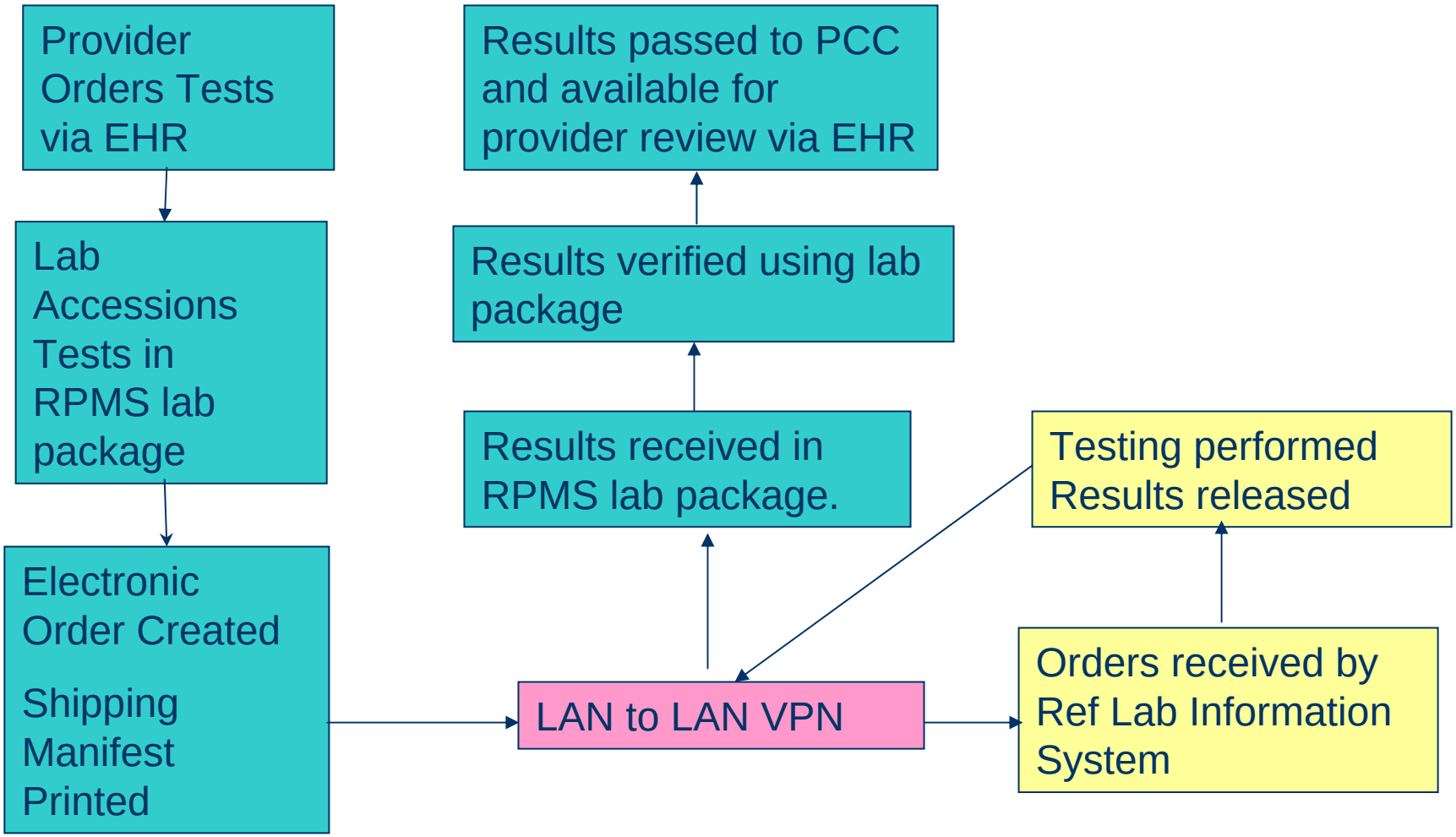
Uni-directional interface



Bi-directional interface

- Must be using the RPMS Lab Package.
- Lab orders placed via Ward Order Entry or EHR.
- Lab order is accessioned which generates an electronic order that is sent to the ref laboratory. This step also creates and prints a “shipping manifest” that is sent along with the specimen to the ref lab.
- Results are received electronically from the ref lab and are reviewed and verified through lab package using the Enter/Verify Data (Auto Instrument) menu option.
- Results available via Interim Reports, Cumulative Reports, Q-Man, PCC, and EHR.

Bi-directional Interface



List of ref labs that have been tested and verified using the interface

Reference Laboratory	Mode
Dynacare	Unidirectional
Laboratory Corporation of America (LabCorp)	Unidirectional and Bidirectional
Quest Diagnostics	Unidirectional and Bidirectional

Reference Laboratory	Mode
Unilab	Unidirectional
Regional Medical Laboratories (RML)	Bidirectional
Sonora Quest Laboratory	Bidirectional
Soft Computer Corporation	Unidirectional

What types of connections are available between the site and reference lab?

2 connectivity choices

1. **Continuous real time streaming** between facility and reference lab via **TCP/IP**.
    - Requires a VPN connection with reference lab.
2. **File Transfer Protocol** (FTP)
    - Requires a VPN connection with reference lab.
    - Orders and test results deposited into an import directory on the RPMS server and orders and results are sent/received at designated time intervals.

VPN connectivity

- VPN tunnels are already established between:
  1. OIT and Quest,
  2. OIT and LabCorp,
  3. OIT and Sonora Quest,
  4. OIT and RML labs
- A site will request to have their RPMS IP address be added to the respective VPN tunnel.
- Must be a coordinated effort between a site, the Area office, the reference laboratory, and OIT networking staff.
- Requests for LAN-LAN VPN connections must submitted to your respective Area offices.
- The Area office will then forward to the OIT Help desk.

VPN connectivity

- Encryption types, IP addresses, port assignments, etc… are issues that are addressed between IHS networking personnel and reference laboratory networking personnel.
- IHS is at the mercy of reference lab networking staff and whether or not ref lab network staff are made available in a timely manner.
- Establishing connectivity between a site and a reference lab can take WEEKS.
- OIT has no control over the reference labs and connectivity is established when they are ready.

FTP connections (Non real-time connections.

- If results and/or orders will be received and/or sent to a ref lab in batch mode, directories must be set up on the RPMS server for storing those files.
- ***REFLAB***, will need to be set up in a public directory on the RPMS server.
- 3 subdirectories – REFLABIN, REFLABOUT, & REFLABSAVE.

We have made the decision to implement the interface, what can I do today?

Reference Laboratory Information

- Prior to implementation, contact your reference lab sales rep, your sales rep will need to:
  1. Submit a project request plan to their respective national office.
  2. Ref lab will begin process of appointing a project team.
  3. Provide the site with test utilization reports.
  4. Provide a compendium of test order and result codes used by the reference lab.
  5. Provide a list of tests requiring “ask at order” questions, i.e. 24 hour Creatinine Clearance test (total volume needed prior to ordering test).

Example of order and result codes used by a reference laboratory.

Component Unit Code	Component Title	Test Code	Test Code Name
100256	DRUG SCREEN(ABUSE),PLASMA	25403600	AMPHETAMINE SCREEN
100256	DRUG SCREEN(ABUSE),PLASMA	25403610	BENZODIAZEPINE SCREEN
100256	DRUG SCREEN(ABUSE),PLASMA	25403620	OPIATE SCREEN
100256	DRUG SCREEN(ABUSE),PLASMA	25403630	COCAINE SCREEN
100256	DRUG SCREEN(ABUSE),PLASMA	25403640	CANNABINOID SCREEN

Component Unit Code	Component Title	Test Code	Test Code Name
100256	DRUG SCREEN(ABUSE),PLASMA	25403600	AMPHETAMINE SCREEN
100256	DRUG SCREEN(ABUSE),PLASMA	25403610	BENZODIAZEPINE SCREEN
100256	DRUG SCREEN(ABUSE),PLASMA	25403620	OPIATE SCREEN
100256	DRUG SCREEN(ABUSE),PLASMA	25403630	COCAINE SCREEN
100256	DRUG SCREEN(ABUSE),PLASMA	25403640	CANNABINOID SCREEN
100308	BETA-2-GLYCOPROTEIN I Ab IgG	11113081	B2-GLYCOPROTEIN I Ab IgG
100309	BETA-2-GLYCOPROTEIN I Ab IgM	11113091	B2-GLYCOPROTEIN I Ab IgM
100410	SYNOVIAL FLUID ANALYSIS	10003253	COLOR
100410	SYNOVIAL FLUID ANALYSIS	10003254	APPEARANCE
100410	SYNOVIAL FLUID ANALYSIS	10003255	RBC
100410	SYNOVIAL FLUID ANALYSIS	10003256	WBC
100410	SYNOVIAL FLUID ANALYSIS	10003257	SEGMENTED NEUTROPHILS
100410	SYNOVIAL FLUID ANALYSIS	10003258	LYMPHOCYTES
100410	SYNOVIAL FLUID ANALYSIS	10003259	MONOCYTES
100410	SYNOVIAL FLUID ANALYSIS	10003260	EOSINOPHILS
100410	SYNOVIAL FLUID ANALYSIS	10003262	MACROPHAGES
100410	SYNOVIAL FLUID ANALYSIS	10003263	LINING CELLS
100410	SYNOVIAL FLUID ANALYSIS	10003264	OTHER CELLS
100410	SYNOVIAL FLUID ANALYSIS	10003265	MUCIN CLOT
100410	SYNOVIAL FLUID ANALYSIS	10003267	FIBRIN CLOT
100410	SYNOVIAL FLUID ANALYSIS	10003268	VISCOSITY
100410	SYNOVIAL FLUID ANALYSIS	10003269	CRYSTALS
100410	SYNOVIAL FLUID ANALYSIS	12008469	COMMENT
100410	SYNOVIAL FLUID ANALYSIS	14003615	TOTAL CELLS COUNTED

Reference lab project officer tasks

- Identify TCPIP addresses and ports that will be used for configuring GIS for the interface.
- Provide you with the settings for the HL7 message structure.
- Provide you with an electronic interface account number(s).
- Essentially, the reference lab project officer's duties consist of marshalling the ref lab's resources and coordinate their efforts with OIT and the site to establish connectivity.

Additional setup steps

Edit the BLR Master Control File in Fileman

- Identify each facility on the RPMS database that will be using the interface by making an entry in the BLR MASTER CONTROL file.
- Multidivisional sites or sites that have more than one location that will be using the interface will need to ensure that each facility has an entry in the BLR Master Control file, that account number(s) are identified for that facility, and a printer has been identified for printing shipping manifests.

PCC Master Control File

- Identify each facility on the RPMS database that will be using the interface by making an entry in the PCC MASTER CONTROL file for the lab package.
- Facilities that have been using the RPMS Laboratory Package will already have this entry.

Initial setup: Uni-directional site

- Build tests in file 60 of lab package for each test that will be performed by a reference lab.
- “Map” each lab test using the order and result codes supplied by the ref lab.
- Update the IHS Lab CPT code file for each lab test in file 60.
- Update the RPMS Provider file with each provider’s UPIN number.
- If UPIN numbers have not been added to the RPMS Provider file, all incoming transactions will be filed in PCC with the generic provider “TECHNICIAN,LAB” as the ordering provider.

“Map” reference lab codes to Laboratory Test File

- Tests in file 60 must be “mapped” to the appropriate order and result codes.
- These codes are supplied by the reference lab and are different for each ref lab.

Component Unit Code	Component Title	Test Code	Test Code Name
100256	DRUG SCREEN(ABUSE),PLASMA	25403600	AMPHETAMINE SCREEN
100256	DRUG SCREEN(ABUSE),PLASMA	25403610	BENZODIAZEPINE SCREEN
100256	DRUG SCREEN(ABUSE),PLASMA	25403620	OPIATE SCREEN
100256	DRUG SCREEN(ABUSE),PLASMA	25403630	COCAINE SCREEN
100256	DRUG SCREEN(ABUSE),PLASMA	25403640	CANNABINOID SCREEN
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100410	SYNOVIAL FLUID ANALYSIS	10003253	COLOR
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100410	SYNOVIAL FLUID ANALYSIS	10003255	RBC
100410	SYNOVIAL FLUID ANALYSIS	10003256	WBC
100410	SYNOVIAL FLUID ANALYSIS	10003257	SEGMENTED NEUTROPHILS
100410	SYNOVIAL FLUID ANALYSIS	10003258	LYMPHOCYTES
100410	SYNOVIAL FLUID ANALYSIS	10003259	MONOCYTES
100410	SYNOVIAL FLUID ANALYSIS	10003260	EOSINOPHILS
100410	SYNOVIAL FLUID ANALYSIS	10003262	MACROPHAGES
100410	SYNOVIAL FLUID ANALYSIS	10003263	LINING CELLS
100410	SYNOVIAL FLUID ANALYSIS	10003264	OTHER CELLS
100410	SYNOVIAL FLUID ANALYSIS	10003265	MUCIN CLOT
100410	SYNOVIAL FLUID ANALYSIS	10003267	FIBRIN CLOT
100410	SYNOVIAL FLUID ANALYSIS	10003268	VISCOSITY
100410	SYNOVIAL FLUID ANALYSIS	10003269	CRYSTALS
100410	SYNOVIAL FLUID ANALYSIS	12008469	COMMENT
100410	SYNOVIAL FLUID ANALYSIS	14003615	TOTAL CELLS COUNTED

“Mapping” menu tree

```
  BLR     IHS Lab Main Support Menu ...
      REFL    Reference Lab Main Menu ...
           MAP  Map Reference Lab Test

Select BLR REFERENCE LAB REFERENCE LAB NAME: QUEST
Select TEST NAMES: HPV DNA, HIGH RISK
 Are you adding 'HPV DNA, HIGH RISK S900489' as a new TEST NAMES (the 2468TH
for this BLR REFERENCE LAB)? No//   Y
Select TEST NAMES: HPV DNA, HIGH RISK S900489//
 LAB TEST POINTER: HPV DNA, HIGH RISK S900489
 ORDER CODE: 900489
 RESULT CODE:
 ORDER ENTRY QUESTION:
 Select ORDER ENTRY RESULT CODE:
Select TEST NAMES: "HPV DNA, HIGH RISK" (duplicate entry using "")
 LAB TEST POINTER: HPV DNA, HIGH RISK S900489
 ORDER CODE:
RESULT CODE: 10900489
 ORDER ENTRY QUESTION:
 Select ORDER ENTRY RESULT CODE:
```

Order code

Result code

Figure 6-7: Mapping reference lab codes to laboratory test file

Initial setup: Bi-directional site

- Build tests in file 60 of lab package for each test that will be performed by a reference lab.
- “Map” each lab test using the order and result codes supplied by the ref lab.
- Update the IHS Lab CPT code file for each lab test in file 60.
- Update the RPMS Provider file with each provider’s UPIN number.
- If UPIN numbers have not been added to the RPMS Provider file, all incoming transactions will be filed in PCC with the generic provider “TECHNICIAN,LAB” as the ordering provider.

Initial setup: Bi-directional site

- Add all orderable tests in the Load/Worklist file of lab package.
- Each test that will have a result will be added to the Auto Instrument file of lab package.
- Units in file 60 will be updated to match those reported by the reference laboratory. Reference ranges and abnormal flags passed from the reference laboratory will be stored with the incoming results.

Whew! I have finished the mapping process. How do I actually “turn” this thing on?

Interface configuration and activation “turns” on the interface.

- RPMS routines for processing incoming and outgoing lab data for different reference laboratories are contained in GIS Patches 13 and 14.
- **You will need to know whether the reference laboratory will be using TCPIP or FTP for transferring test results**.
- *The TCPIP address and ports assigned by the reference laboratory for sending orders and receiving results must be known before attempting to activate the interface.*
- The reference laboratory may supply both test server information as well as production server information.

Reference Lab Site Parameter Setup

- The final step in activating the reference laboratory interface involves setting up the site parameters for that interface.
- Settings to be used for site parameters will be provided by your reference laboratory.

Ref Lab site parameter example

TCPIP Address -156.30.21.204
Sending Port (Orders for bidirectional interface) - 56285
Receiving Port (Results for unidirectional/bidirectional interfaces) - 56286
Sending Application - NW98134731 (MSH 3)
Sending Facility - 98134731 (MSH 4)
Receiving Application - QUEST (MSH 5)
Receiving Facility - TSE (MSH 6)
Processing ID - T (MSH 11)

OK, I have installed lab patch 21, I have edited Fileman files, I have built tests in file 60 and mapped them, I have configured the interface, & I have placed all IP addresses and port numbers where they should be. Is there anything else I need to know?

Additional RPMS routines that must be scheduled

- TASKMAN - BLRTASK LAB LOG CLEANUP purges “old” transaction log records.
- INH AUTOPURGE - deletes raw data in the Universal Interface file.
- BLR REFLAB RESTART RECEIVER
- BLR REFLAB RESTART TRANSMITTER
- The last two tasks restart the GIS receiver and transmitter on an hourly basis in the event connectivity is lost.

Mail Groups

- Mail groups should be set up to receive bulletins notifying them of reference laboratory tests that failed to pass to PCC.
- Members should be the site manager and the primary person(s) on site who will be managing the tests imported and/or exported from the Reference Laboratory.
- Directions for researching and dealing with failed transactions are provided in the Maintenance Section of the User Manual.

Security Keys

- **BLRRLZ -** access to the Reference Laboratory interface menu.
- **BLRZMENU** – allow one to view the status of the link to PCC, edit CPT codes, and re-file transactions.
- FileMan access code of **LI**
- Other keys are found in the user manual.

Menu Management

- The ref lab main menu will contain options to:
  1. map laboratory test codes to reference laboratory test codes,
  2. export and import files to or from the Reference Laboratory (FTP sites only),
  3. set site parameters,
  4. review and verify incoming data for a uni-directional interface,
  5. enable users to check the status of the GIS processors and restart them if necessary.

Examples of actual data that passes through a live interface.

Shipping manifest

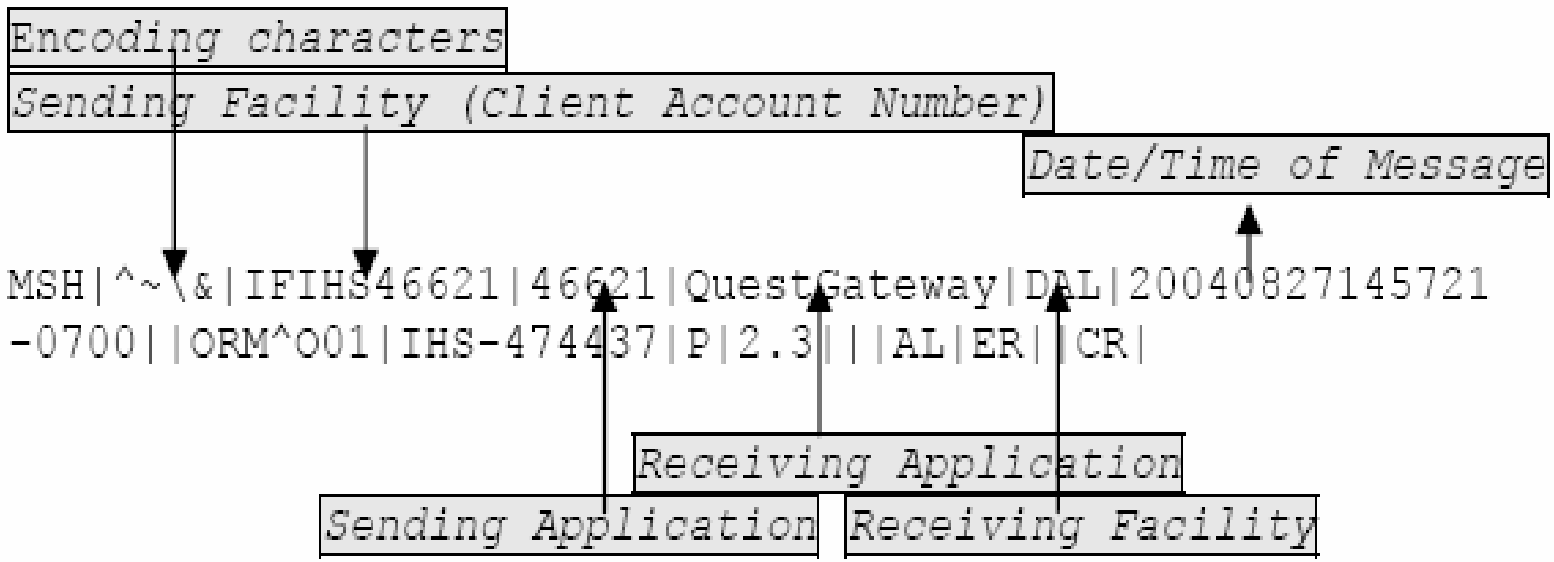
```
                  INDIAN HEALTH SERVICE EREQ            PAGE: 1 of 1

REF LAB NAME: LABCORP                       CLIENT #: 02305092

FACILITY: LITTLE BUILDING HOSPITAL          Dec 29, 2003@16:21:38
ADDRESS: P.O. BOX 187, DULCE,  87528
================================================================================

ORDER (Control): 13334                      ORDER DATE: Dec 29, 2003      MID:
PATIENT: TEST,PATIENT CHILD                 CHART (Patient ID): 088888
SEX: M    DOB: AUG 8,2000
LOCATION: OP                                            Bill Type: Client
PRACTITIONER: MILLS, CHRISTOPHER                        UPIN: 320057
LAB ARRIVAL (COLLECTION DATE/TIME): Dec 29, 2003@10:00


TEST NAME: LEAD, PEDIATRIC (724500)                SAMPLE: BLOOD
SOURCE: BLOOD                                      ACCESSION: 6003000233
                                                   URGENCY: ROUTINE

ORDER ENTRY QUESTIONS:
     Race?(1=White,2=Black,3=Indian,4=Asian,5=Other)3
     Hispanic (1=Yes,2=No,9=Unknown)               2
     Type? (U=Urine,V=Venous,F=Fingerstick)        F
     Purpose? (I=Initial,R=Repeat,F=Follow-up)     I
     County Code? (2 Digit County Code)            02
```

Figure 6-9: Shipping manifest example

MSH

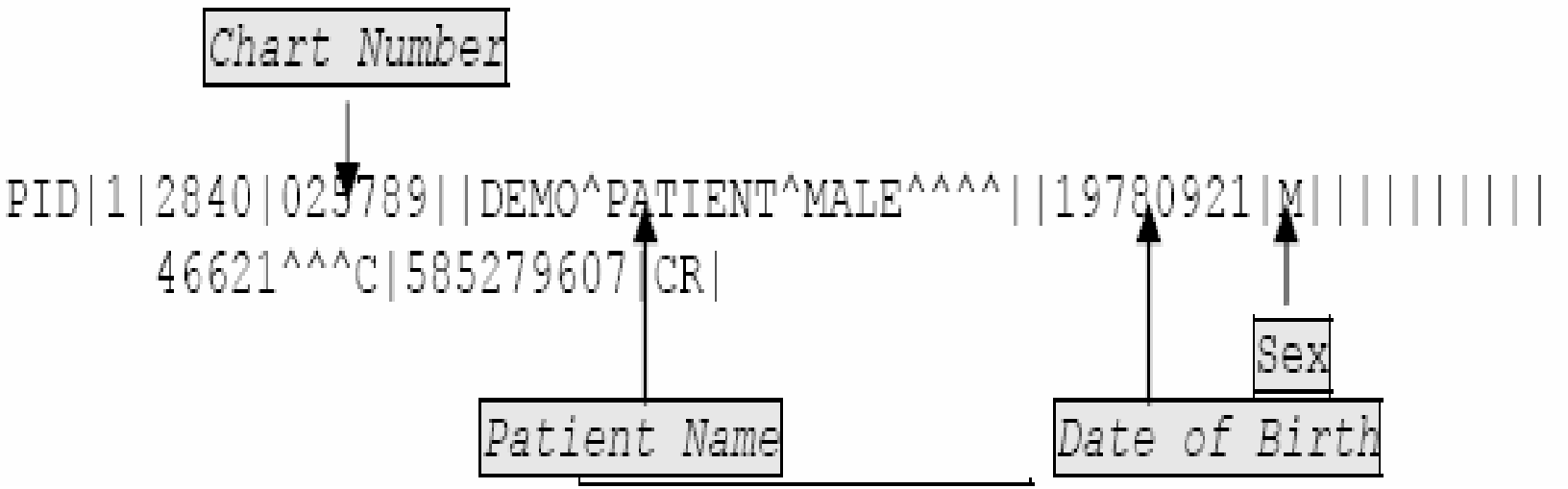
MSH is the message header. It identifies the sending and receiving facilities, the client account number, and date and time of message. The MSH segment is essentially the "address" on a message.

3.1.1 An Order Message



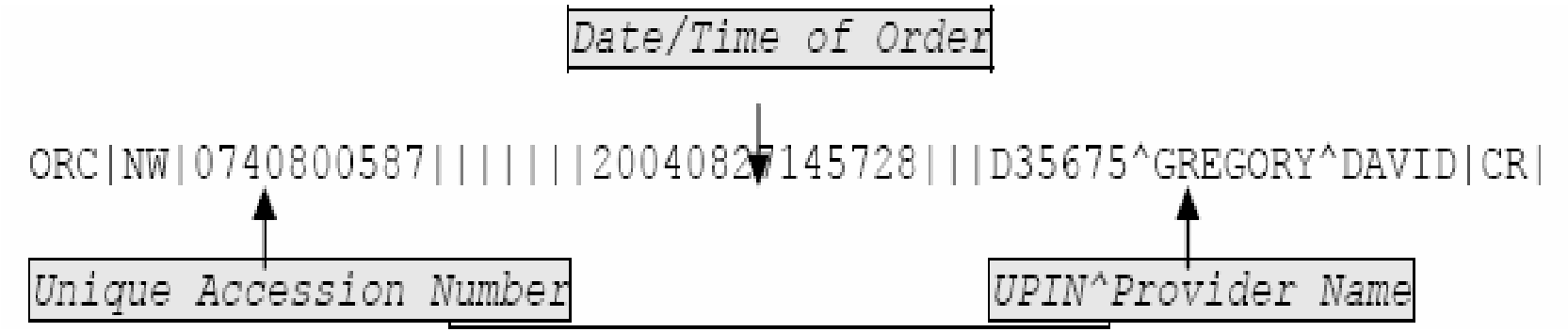
PID

The PID is the patient identifier segment.



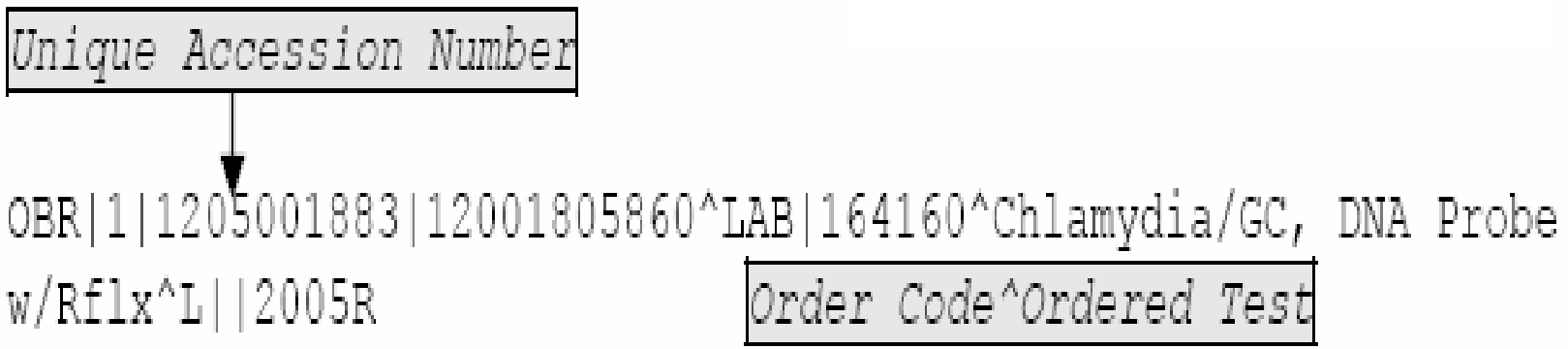
ORC

ORC is additional order information. It includes the accession number, date and time of accession, and ordering provider.



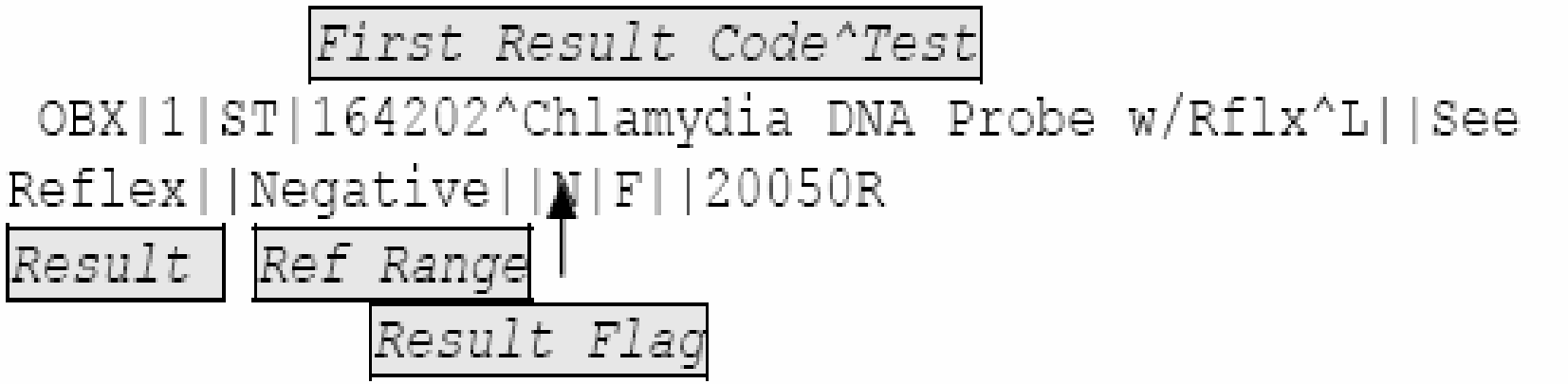
OBR

OBR is the order segment.



OBX

OBX is the result segment.



OBX is the result segment
NTE is the comment segment

Reflex Result 1

```
OBX|1|ST|164200^C. trachomatis -
PCA^L||Positive||Negative|A|N|F||200505031532R
NTE|1|L|Performed At: DA|CR
NTE|2|L|LabCorp Dallas|CR
NTE|3|L|7777 Forest Lane Suite 350C|CR
NTE|4|L|Dallas, TX 752300000|CR
```

Example of the final product

```
DEMO,PATIENT FEMALE                                          07/09/2004 8:03
     HRCN: 999996    SEX: F    AGE: 32    LOC: OPDL

       Provider: PROVIDER, TEST
       Specimen: SERUM
Accession [UID]: QUEST 0700 88 [0740700088]

                                07/08/2004 09:00
   Test name                  Result    units      Ref.   range
   CEA-Q 978                   <0.4     ng/mL
   Eval: NON-SMOKER:     <2.5
   Eval:     SMOKER:     <5.0
   Eval: Because the concentration of CEA in any given specimen can vary due
   Eval: to differences in assay methods and reagent specificity, values
   Eval: from different assay methods cannot be used interchangeably.
   Eval: Serum CEA levels, regardless of value, should not be interpreted
   Eval: as absolute evidence of the presence or absence of disease.
   Eval: CEA is not intended for use as a cancer screening test.
Comment: NON-SMOKER:  <2.5
             SMOKER:  <5.0
         BECAUSE THE CONCENTRATION OF CEA IN ANY GIVEN SPECIMEN CAN VARY DUE
         TO DIFFERENCES IN ASSAY METHODS AND REAGENT SPECIFICITY, VALUES FROM
         DIFFERENT ASSAY METHODS CANNOT BE USED INTERCHANGEABLY.  SERUM CEA
         LEVELS, REGARDLESS OF VALUE, SHOULD NOT BE INTERPRETED AS ABSOLUTE
         EVIDENCE OF THE PRESENCE OR ABSENCE OF DISEASE.  CEA IS NOT INTENDED
         FOR USE AS A CANCER SCREENING TEST.

         Test Performed at:
         QUEST DIAGNOSTICS-IRVING
```

Test name & result

Figure 6-18: "Immediate Print" Interim Report sample with duplicate interpretation and comments

Questions?